

Notice of Allowability

Application No.

09/610,935

Examiner

Bradley L. Sisson

Applicant(s)

WARD ET AL.

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1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to interview of 10 November 2004.
2. ☒ The allowed claim(s) is/are 13-16, 20, 42-53 and 60-83.
3. ☒ The drawings filed on 01 March 2002 are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

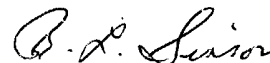
Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
 6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892).
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☒ Interview Summary (PTO-413), Paper No./Mail Date _____
7. ☒ Examiner's Amendment/Comment
8. ☐ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____



Bradley L. Sisson
Primary Examiner
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EXAMINER'S AMENDMENT

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.
2. Authorization for this examiner's amendment was given in a telephone interview with Timothy B. McBride, Reg. No. 47,781 on 10 November 2004.

The application has been amended as follows:

21. Canceled.
 22. Canceled.
 60. (Currently amended) An aqueous reagent for use in forming a polymerase reaction mixture comprising a thermostable DNA polymerase, a nucleic acid polymer template, a primer, nucleotides, a detectible anionic tracer dye unbound to primer or nucleotides, and a solute to increase the physical density of the reagent, the reagent comprising the thermostable DNA polymerase, the detectible anionic tracer dye, and the solute, the reagent but being substantially free of the primer and the nucleic acid polymer template, ~~the reagent~~ and having an optical density of about 5 to about 500 at a visible wavelength of maximal tracer absorbance and a physical density of at least about 1.01 gm/cm³, but less than the density of the solute.
 66. (New) An aqueous reagent for use in forming a polymerase reaction mixture comprising a thermostable DNA polymerase, a nucleic acid polymer template, a primer, nucleotides, a detectible anionic tracer dye unbound to primer or nucleotides, and a solute to increase the physical density of the reagent, the reagent comprising the thermostable DNA
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polymerase, the detectible anionic tracer dye wherein the tracer dye comprises acid violet 5 and acid red 1, and the solute, the reagent being free of the primer and the nucleic acid polymer template, and having an optical density of about 5 to about 500 at a visible wavelength of maximal tracer absorbance and a physical density of at least about 1.01 gm/cm^3 , but less than the density of the solute.

67. (New) The reagent of claim 66 wherein the thermostable DNA polymerase is Taq polymerase.

68. (New) The reagent of claim 66 wherein the thermostable DNA polymerase is Taq and the concentration of Taq in the reagent is 0.033 to 10 units/ μl .

69. (New) The reagent of claim 66 wherein the thermostable DNA polymerase is Taq and the concentration of Taq in the reagent is 0.06 to 5 units/ μl .

70. (New) The reagent of claim 66 wherein the thermostable DNA polymerase is Taq and the concentration of Taq in the reagent is about 1 unit/ μl .

71. (New) The reagent of claim 67, wherein the solute is sugar, trimethylglycine, or glycerol.

72. (New) The reagent of claim 67, wherein the solute is glycerol.

73. (New) An aqueous reagent for use in forming a polymerase reaction mixture comprising a thermostable DNA polymerase, a nucleic acid polymer template, a primer, nucleotides, a detectible anionic tracer dye unbound to primer or nucleotides, and a solute to increase the physical density of the reagent, the reagent comprising Taq polymerase, the detectible anionic tracer dye consisting of 20% acid violet 5 and 80% acid red 1, and the solute, the reagent being free of the primer and the nucleic acid polymer template, and having an optical

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density of about 200 to about 400 at a visible wavelength of maximal tracer absorbance and a physical density of at least about 1.01 gm/cm^3 , but less than the density of the solute.

74. (New) The reagent of claim 73 wherein the thermostable DNA polymerase is Taq polymerase.

75. (New) The reagent of claim 73 wherein the thermostable DNA polymerase is Taq and the concentration of Taq in the reagent is 0.033 to 10 units/ μl .

76. (New) The reagent of claim 73 wherein the thermostable DNA polymerase is Taq and the concentration of Taq in the reagent is 0.06 to 5 units/ μl .

77. (New) The reagent of claim 73 wherein the thermostable DNA polymerase is Taq and the concentration of Taq in the reagent is about 1 unit/ μl .

78. (New) The reagent of claim 74, wherein the solute is sugar, trimethylglycine, or glycerol.

79. (New) The reagent of claim 74, wherein the solute is glycerol.

80. (New) The reagent of 42 wherein the reagent has a peak visible absorbance wavelength at between 500 and 535.

81. (New) The reagent of 80 wherein the reagent has a density of about 1.14 g/cm^3 .

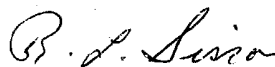
82. (New) The reagent of 81 wherein the solute comprises glycerol, trimethylglycine or a sugar.

3. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bradley L. Sisson whose telephone number is (571) 272-0751.

The examiner can normally be reached on 6:30 a.m. to 5 p.m., Monday through Thursday.

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4. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones can be reached on (571) 272-0745. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.
5. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Bradley L. Sisson
Primary Examiner
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BLS
15/11/2004